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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,866	07/07/2003	Jane Hirsh	CP 100	8191
23579 PATREA L. P.	23579 7590 03/29/2007 PATREA L. PABST		EXAMINER	
PABST PATENT GROUP LLP 400 COLONY SQUARE, SUITE 1200 1201 PEACHTREE STREET ATLANTA, GA 30361			CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	
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SHORTENED STATUTOR	RY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MC	ONTHS	03/29/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)
	10/614,866	HIRSH ET AL.
Office Action Summary	Examiner	Art Unit
	Lakshmi S. Channavajjala	1615
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be timulated the second will expire SIX (6) MONTHS from cause the application to become ABANDONE!	I. lely filed the mailing date of this communication. D (35 U.S.C. § 133).
Status		
1) ■ Responsive to communication(s) filed on <u>08 December</u> 2a) ■ This action is FINAL . 2b) ■ This 3) ■ Since this application is in condition for allower closed in accordance with the practice under Expression is the practice of	action is non-final. nce except for formal matters, pro	
Disposition of Claims		
4) ☐ Claim(s) 1-13,15-29 and 33-38 is/are pending if 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-13,15-29 and 33-38 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or are subject to restriction and/or are subject to by the Examine 10) ☐ The drawing(s) filed on is/are: a) ☐ according and are subjected to by the Examine 10) ☐ The drawing(s) filed on is/are: a) ☐ according and are subjected to by the Examine 10) ☐ The drawing(s) filed on is/are: a) ☐ according and are subjected to by the Examine 10) ☐ The drawing(s) filed on is/are: a) ☐ according and are subjected to by the Examine 10) ☐ The drawing(s) filed on is/are: a) ☐ according and are subjected to by the Examine 10) ☐ The drawing(s) filed on is/are: a) ☐ according and are subjected to by the Examine 10) ☐ The drawing(s) filed on is/are: a) ☐ according and are subjected to by the Examine 10) ☐ The drawing(s) filed on is/are: a) ☐ according and are subjected to by the Examine 10) ☐ The drawing(s) filed on is/are: a) ☐ according and are subjected to by the Examine 10) ☐ The drawing(s) filed on is/are: a) ☐ according and are subjected to by the Examine 10) ☐ The drawing(s) filed on is/are: a) ☐ according and are subjected to by the Examine 10) ☐ The drawing(s) filed on is/are: a) ☐ according and are subjected to by the Examine 10) ☐ The drawing(s) filed on is/are: a) ☐ according and are subjected to by the Examine 10) ☐ according and are subjected to by the Examine 10) ☐ according and are subjected to by the Examine 10) ☐ according and are subjected to by the Examine 10 ☐ according and are subjected to by the Examine 10 ☐ according and are subjected to by the Examine 10 ☐ according and are subjected to by the Examine 10 ☐ according and are subjected to by the Examine 10 ☐ according and are subjected to by the Examine 10 ☐ according and are subjected to by the Examine 10 ☐ according an	vn from consideration. r election requirement. r. epted or b) □ objected to by the following(s) be held in abeyance. See	e 37 CFR 1.85(a).
11)☐ The oath or declaration is objected to by the Ex		
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list	s have been received. s have been received in Applicati rity documents have been receive u (PCT Rule 17.2(a)).	on No ed in this National Stage
Attachment(s)		·
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate

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DETAILED ACTION

Receipt of amendment and response dated 12-8-06 is acknowledged.

Claims 1-13, 15-29 and 33-38 are pending in the instant application. Claims 14 and 30-32 have been canceled.

Applicants have made substantial amendments to the pending claims. In view of the previously made election requirement and the present amendments, it is to be noted that claims 2 (independent claim), 4-7, 9-13, 15-26 and 33-36 read on the elected species i.e., a lipophilic derivative of a drug. Accordingly, claims 2, 4-7, 9-13, 15-26 and 33-36 have been considered for examination and claims 1, 3, 8, 27-29 and 37-38 have been withdrawn as being non-elected.

Response to Arguments

Applicant's arguments with respect to claims 1-13, 15-29 and 33-38 have been considered but are most in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim2, 4-7, 9-13, 16-26 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,310,072 to Smith et al (Smith) in view of US 6,696,088 (Oshlack et al).

Smith teaches pharmaceutical compositions comprising a combination of mu and kappa opioid agonists such as morphine and oxycodone respectively. In particular,

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Smith teaches salts of the opioid agonists such as pectinate and terephthalate, both of which have been described in the instant application as lipophilic derivatives (col. 5, L 5-10, L 41-43). Smith suggests oral and subcutaneous methods of administering the composition, wherein the controlled release dosage forms are coated with hydrophobic polymers such as higher fatty alcohols (col. 8, L 49-63). While the reference suggests controlled release as well as immediate release of the drugs, Smith does not teach a formulation of oxycodone that is dispersed in the insoluble formulation for preventing the immediate release of the drug upon loosing its integrity.

Oshlack teaches a tamper resistant and also abuse resistant oral opioid formulation, in which the active agent is not delivered immediately (col. 5, col. 6, L 42-60 & lines bridging col. 8-9). Oshlack teaches the same active agents that are claimed and in particular oxycodone (entire col. 14 & col. 16, L 1-19) and suggests salts of the opioid compounds such as sulfates, methanesulfonate, benzenesulfonates, phosphates etc (col. 11, L 45-61), which are dispersed in a non-releasable matrix or as coated particles made of hydrophobic and water-insoluble material. The latter hydrophobic material is selected from the group consisting of ethyl cellulose, cellulose acetate phthalate, acrylic polymers, fatty acids, fatty alcohols, waxes etc (col. 27, L 25-col. 29, L 37). Preferably, Oshlack teaches hydrophobic materials such as waxes, fatty acids etc (col. 28, L18-54). Oshlack further teaches coating of the non-releasable dosage forms with materials such a shellac, zein etc (col. 23, L 2-12), which admittedly reads on the enzyme degradable coating of the instant claims. Oshlack also teaches microparticles, coated microparticles and enteric coating materials such

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Thus, Oshlack is also in the same field of endeavor as that of the instant i.e., preparing abuse resistant formulations of opioid analgesics and delaying the immediate release of the drug that results in abuse of the substance.

While instant claims recite lipophilic derivatives of the drug, Oshlack teaches salts of the opioid drugs such as organic amine salts (picoline, ethanolamine, triethanolamine, dibenzyldiethyldiamine etc., (col. 11, L 45-52), which read on the instant lipophilic derivatives.

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the controlled release formulation i.e., the insoluble material selected from fats, fatty alcohols, waxes and insoluble cellulose polymers of Oshlack for preparing a controlled release dosage formulation of terephthalate or pectinate salt of oxycodone because Oshlack teaches that opioid analgesics have a potential for the development of tolerance and physical dependence with repeated opioid use resulting in addiction (abuse) and that the abuse can be controlled by sequestering the bioavailability of the drug upon administration i.e., by preventing the immediate availability of the drug.

2. Claims 15 is are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,310,072 to Smith et al (Smith) in view of US 6,696,088 (Oshlack et al) as applied to claims s 2, 4-7, 9-10, 16-26 and 33-36 above, and further in view of US 6,048,736 to Kosak or US 5,756,483 to Merkus ('483, previously cited in the non-final rejection).

Smith and Oshlack, discussed above, do not teach the claimed complexes in particular the cyclodextrin complexes.

Kosak teaches cyclodextrin polymers for carrying drugs and other active agents and for controlled release of active agents. Kosak teaches that when the polymers are conjugated to the cyclodextrin molecules, the drugs can be designed solely for efficacy without regard for solubility and their targeted release. Kosak teaches employing a number of active agents with cyclodextrin including narcotics (col.3).

'483 teach compositions comprising morphine, apomorphine, ergotamine etc., compounds and their administration in combination with cyclodextrin or a polysaccharide (abstract, examples and col. 4, lines 50-67). '483 teach that cyclodextrin and other saccharides increase the stability of the drug and thus increase their bioavailability. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to prepare morphine and oxycodone compositions comprising cyclodextrin because both Kosak and '483 suggests that drug complexes with cyclodextrin improves the solubility and their targeted release. A skilled artisan would have expected to release the drug combination of Smith in a delayed (Oshlack) and yet targeted fashion (Kosak) so as to further improve drug abuse of the opioid drugs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615 March 20, 2007

> LAKSHMI S. CHANNAVAJJALA PRIMARY EXAMINER